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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/814,404 | 03/31/2004 | Samuel Achilefu | MRD / 54DV | 5388 |

7590 08/21/2006

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EXAMINER

PERREIRA, MELISSA JEAN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1618

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/814,404

Applicant(s)

ACHILEFU ET AL.

Examiner

Melissa Perreira

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 4-14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/21/04; 6/3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 6/3/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; **each non-patent literature publication** or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information that is crossed out has not been considered.

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The parent application number is listed incorrectly on the bibliographic data sheet and is omitted from the oath and declaration. The incorrect parent application number listed on the bibliographic data sheet is 09/688,649. Therefore the instant claims do not receive the benefit of the parent application date and are examined in regards to the effective filing date.

Election/Restrictions

1. Applicant's election of Group I, claims 1-3 and 15 and the species R_3 is C_1 alkyl, each of R_4 , R_5 , R_6 and R_7 is H, Y_1 is $-CH_2-(CH_2-O-CH_2)_1-CH_2CO_2^-$, W is $-C(CH_3)_2$, e is 1 and T is a negative charge in the reply filed on 7/28/06 is acknowledged. Because

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applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The search of the elected species wherein R_3 is C_1 alkyl, each of R_4 , R_5 , R_6 and R_7 is H, Y_1 is $-CH_2-(CH_2-O-CH_2)_1-CH_2CO_2^-$ was performed and extended to include the species 1-(4-sufobutyl)-2,3,3,3-trimethyl-3H-indolenine, 1-(4-sulfobutyl)-2,3,3-trimethyl-5-sulfoindolenine and 5-carboxymethyl-2,3,3-trimethyl-3H-indolium-1-(4'sulfobutyl)-betaine. The requirement is still deemed proper and is therefore made **FINAL**.

3. Claims 4-14 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/28/06.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

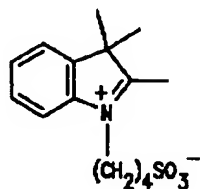
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,2 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Licha et al. (WO98/47538 as translated in US 6,534,041B1).

3. Licha et al. (WO98/47538 as translated in US 6,534,041B1) teaches optic diagnostic and therapeutic agents/dyes and the use of 1-(4-sulfobutyl)-2,3,3,3-trimethyl-

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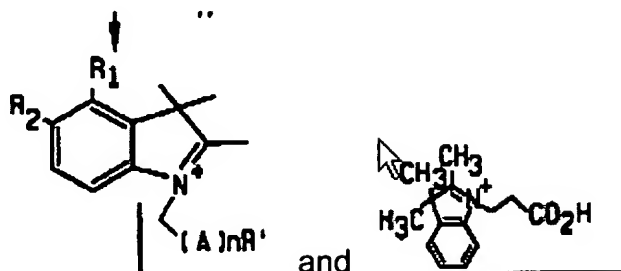
3H-indolenine **3** (below), as a precursor in the synthesis of the diagnostic dyes, with near infrared radiation (figure 1; column 1, lines 9-14; column 8, lines 29-30).

**3**

4. Claims 1,2 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohno et al. (US 4,839,265A).
5. Ohno et al. (US 4,839,265A) teaches of the use of known compound 1-(4-sulfobutyl)-2,3,3-trimethyl-5-sulfoindolenine in the synthesis of water-soluble dyes for use as photographic emulsions with good sensitivity in the infrared region (column 2, lines 45+; column 11, lines 59+).
6. Claims 1,2 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Southwick et al. (*OPPI Briefs*, 1988, 20, 279-284).
7. Southwick et al. (*OPPI Briefs*, 1988, 20, 279-284) teaches of an intermediate for water-soluble cyanine dyes, 5-carboxymethyl-2,3,3-trimethyl-3H-indolium-1-(4'sulfobutyl)-betaine (p280, figure and paragraph 2).
8. Claims 1-3 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Achilefu et al. (US 6,180,085B1).
9. Achilefu et al. (US 6,180,085B1) teaches that the compounds found in figure 1 or figure 5 (below; sheet 1; sheet 3) have been utilized, as a precursor to the indocyanine

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dyes suitable for biomedical applications. R_1 and R_2 may be H, A is CH_2 or CH_2OCH_2 and R' is COOH or SO_3 .



Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

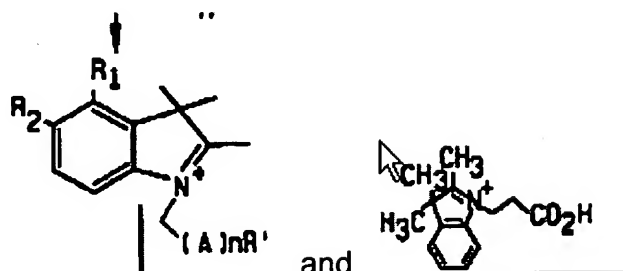
11. Claims 1-3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Licha et al. (WO98/47538 as translated in US 6,534,041B1) in view of Achilefu et al. (US 6,180,085B1).

12. Licha et al. (WO98/47538 as translated in US 6,534,041B1) discloses optic diagnostic and therapeutic agents/dyes and the use of 1-(4-sulfobutyl)-2,3,3,3-trimethyl-3H-indolenine 3 (below) as a precursor in the synthesis of the diagnostic dyes; see above. Licha et al. (WO98/47538 as translated in US 6,534,041B1) does not disclose Y_1 of the instant claims is $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_1-\text{CH}_2\text{CO}_2^-$.

13. Achilefu et al. (US 6,180,085B1) teaches that the compounds found in figure 1 or figure 5 (below; sheet 1; sheet 3) have been utilized, as a precursor to the indocyanine

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dyes suitable for biomedical applications. R_1 and R_2 may be H, A is CH_2 or CH_2OCH_2 and R' is COOH or SO_3 .



14. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the Y_1 substituent $-(\text{CH}_2)_4\text{SO}_3^-$ of Licha et al. for the $-\text{CH}_2-(\text{CH}_2-\text{O}-\text{CH}_2)_1-\text{CH}_2\text{CO}_2^-$ substituent of Achilefu et al. (US 6,180,085B1) to improve the clearance capabilities of the hydrophilic anionic indole disulfonate, prevent aggregation and improved their dendrimer forming abilities to ultimately make them more efficient diagnostic agents.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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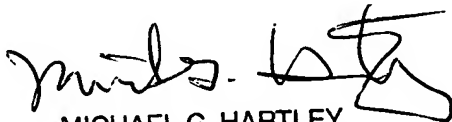
published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP

August 1, 2006



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER